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10/716,107	11/18/2003	Naomi L. Nakao	G30-017	6124

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R. Neil Sudol
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER

MENDOZA, MICHAEL G

ART UNIT PAPER NUMBER

3734

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,107

Applicant(s)

NAKAO, NAOMI L.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1--6, 9, 14, 17-23, and 25 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 10-13, 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/2/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 18-25 are objected to because of the following informalities: there are two claim 18's. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 11 recites the limitation "said backbone" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

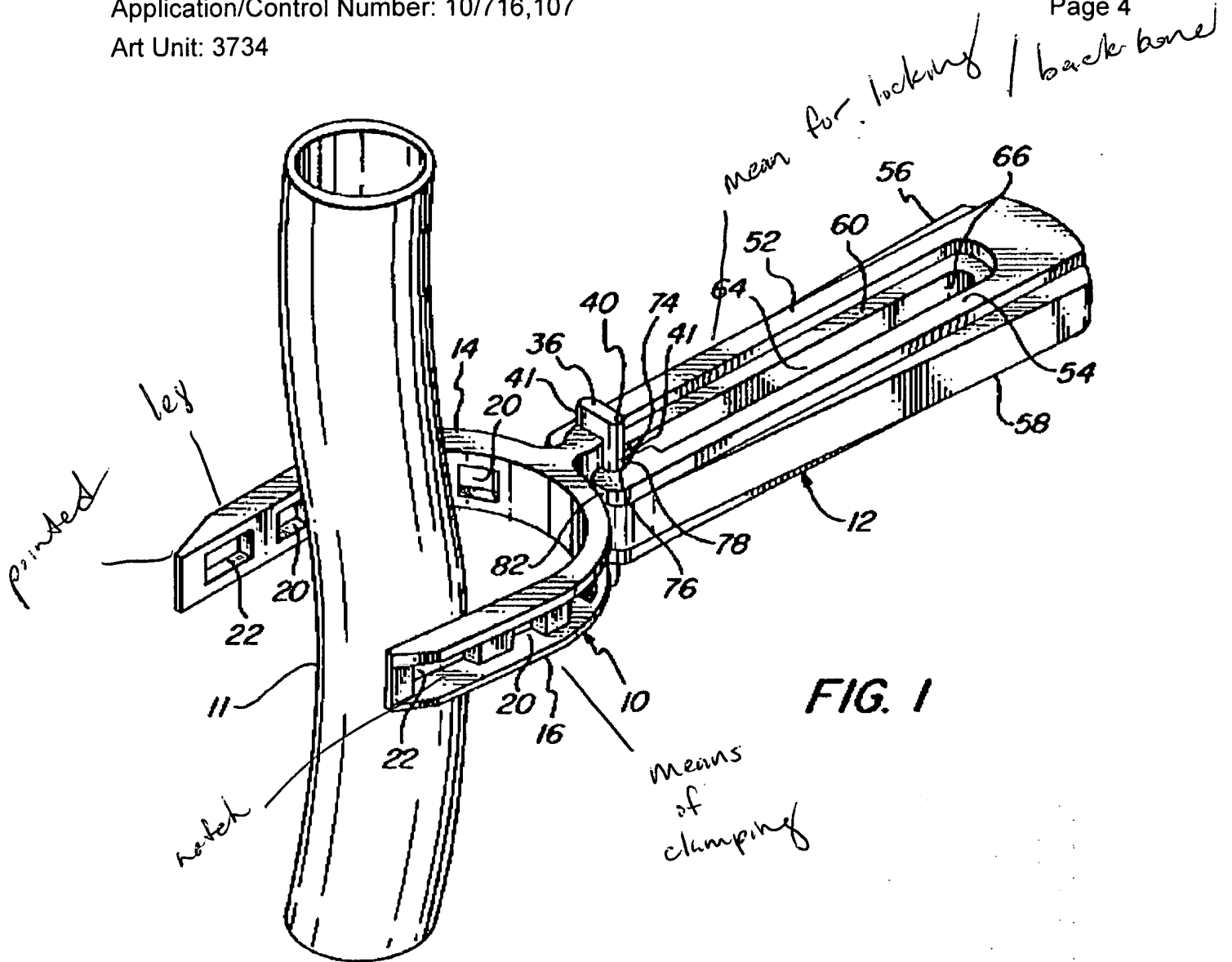
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 17-18, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Conners 5306286.
7. Conners teaches a staple assembly comprising: means for clamping or securing tissue inside of the body; means, engageable with the means for clamping or securing, for locking the staple in a closed position once the staple is positioned and closed on

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desired tissue; wherein the means for clamp in or securing inside the body comprising a staple capable of being opened and closed, the staple being biased to an opened position, the staple having a biased open position angle that is greater than an open position angle of a staple holder component; wherein the staple is insertable into tissue; wherein the staple is made from shape memory or flexible metal; wherein the means for locking includes a backbone element, the staple having notches along a back of the staple to guide, accept, and secure the backbone to the staple; wherein the means for clamping or securing includes opposing legs of a single folded over member, the legs being formed in an arc configuration, the legs having distal tips that touch when the legs are in a closed position, the distal tips of the legs being pointed.



8. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Wolfe, Jr. et al. 4667823.

9. Wolfe, Jr. et al. teaches a tray with a plurality of first preformed holes, the tray also including a plurality of second preformed holes aligned with respective ones of the first preformed holes. The applicant has not positively claimed the staples. The limitation for holding staples is a functional limitation and is not given any patentable weight.

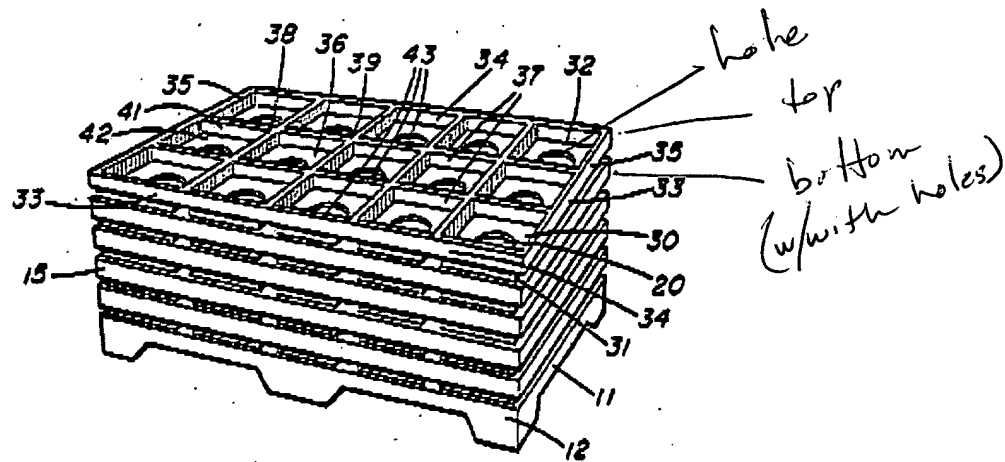


FIG. 3

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-5, 6, 9, 14, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable Deniega 4590937.

12. Deniega teaches an stapling assembly comprising: a staple; means for securing the staple in a closed position; means for providing a working channel; and means for holding the staple during deployment. It should be noted that Deniega fails to specifically teach means for hold additional staples. However, it is well known in the art or packaging staples to provide a means for holding loose staples that are not in use. Therefore it would have been obvious to one having ordinary skill in the art at the time

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the invention was made to package the staples for holding staples not in use so the staples will not be lost or scattered.

13. Deniega teaches the stapling assembly in accordance with claim 1, wherein the staple is biased to an open position having an open-position angle greater than an open-position angle of the staple holder component; wherein the staple is insertable into tissue; wherein the staple has notches along a backside of the staple; wherein the staple is configured with opposing legs of a single folded over material, the legs formed in an arc configuration, the legs having distal tips that touch one another when the staple is closed, the distal tips of the legs being pointed; and wherein the means for providing a working channel comprises a distal end connected to a staple deployment mechanism, a proximal end connected to an actuation and handle mechanism; the means for providing a working channel comprising at least one lumen-forming elongate tube made of a flexible material and having a proximal and distal end (col. 4, lines 15-23).

14. As to claim 4, Deniega discloses the claimed invention except for the staple being made from shape memory or flexible metal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a shape memory metal, since it has been held to be with the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient strength for the intended use of the material. Deniega teaches the use of a resilient material (col. 1,

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lines 20-28). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shape memory metal for its common property of being resilient.

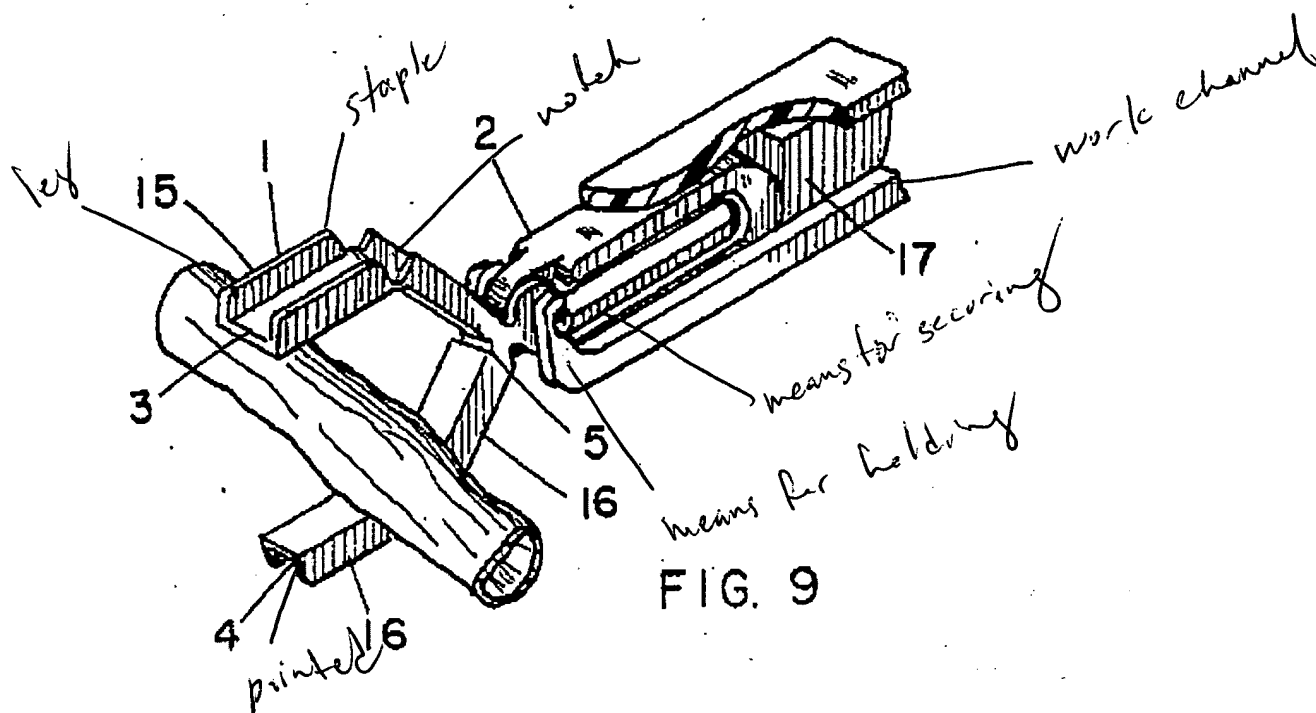
15. As to claim 9, Deniega discloses the claimed invention except for the means for holding and manipulation comprises metal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use metal, since it has been held to be with the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient strength for the intended use of the material.

16. As to claim 22, Deniega teaches a staple and stapler assembly, with means for securing the staple in a closed position once the staple is positioned and closed on desired tissue, the means for securing comprising a backbone made of rigid material, capable of being slid over a backside of the staple and being secured firmly over the closed staple, locking into place over the closed staple. It should be noted that Deniega fails to teach jaws. Deniega does teach means for holding as shown in fig. 9. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use jaws as an alternative means for holding the staple of Deniega as opposed to the hook like structure taught by Deniega.

17. As to claim 23, Deniega teaches the staple and stapler assembly in accordance with claim 22, further comprising means for advancing the backbone over the staple, the

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means for advancing comprising a push bar, it would be inherent that the push bar have some type of handle to allow manipulation of the push bar (col. 4, lines 24-26).



18. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conners.

19. Conners discloses the claimed invention except for the staple being made from shape memory or flexible metal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a shape memory metal, since it has been held to be with the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient strength for the intended use of the material. Conners teaches the use of a resilient material (col. 2, lines 52-53). Therefore it would

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have been obvious to one of ordinary skill in the art at the time the invention was made to use a shape memory metal for its common property of being resilient.

Allowable Subject Matter

20. Claim 24 is allowable over the prior art of record.

21. Claims 7, 8, 10-13, 15, and 16 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of an endoscopic staple and stapler assembly for securing tissue internal to the body, comprising: a staple holder component including a pair of formed opposing jaws, opposing edges of the jaws being formed to securely hold the staple, the jaws being adapted to enter and grasp tissue, the jaws being attached to a drive mechanism that opens and closes the jaws, the jaws grasping targeted tissue and clamping the staple closed over the tissue while the backbone is slid over the closed staple.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM

4/14/2006

GARY JACKSON
PRIMARY EXAMINER
GROUP 3300
